K063184

510(k) Summary

NOV - 3 2006

Date:	September 8, 2006
Submitter's Name:	Toshiba America Medical Systems, Inc.
Submitter's Address:	P.O. Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Submitter's Contact: (714)730-5000	Paul Biggins, Regulatory Affairs Specialist,
Establishment Registration Number:	2020563
Device Proprietary Name:	CVV-001A, Vessel View Software
Common Name: 90JAK]	Scanner, Computed Tomography, X-Ray [Fed. Reg. No. 892.1750, Pro. Code:
Regulatory Class:	**II (per** 21 CFR 892.1750)
Performance Standard: Standard	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment
Predicate Device(s):	GE CardIQ Analysis II; k020796
Reason For Submission	Modification of cleared device

Description of this Device:
The CVV-001A will be added to the previously cleared TSX-101A Aquilion CT system. This addition requires software modifications to the existing device. Addition of this option will provide trained physicians with visualization and measurements tools for assessing blood vessels.

Summary of Intended Uses:
CVV-001A is designed to facilitate the assessment of blood vessels by a trained physician in that it provides display and measurements tools.

Technological Characteristics:
This package is similar in uses and applications as those of the predicate devices. The main difference is in the method used to obtain the final results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Toshiba America Medical Systems, Inc.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, N.W.
BUFFALO MN 55313

NOV - 3 2006

Re: K063184
Trade/Device Name: CVV-001A, Vessel View Software
Regulation Number: 21 CFR §892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: October 16, 2006
Received: October 20, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K06 3184

Device Name: CVV-001A, Vessel View Software

Indications For Use:

CVV-001A, Vessel View Software is a post processing software option for the TSX-101A CT system. This product can be used for the analysis of CT angiography images. It provides display and measurement tools that can aid trained physicians for visualizing and assessing various blood vessels.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063184